INDEC SYSTEMS, INC.

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K062985

NOV 2 2 2006

510(k) Summary

As required by section 807.92

Submitted by: INDEC Systems, Inc.
2210 Martin Ave.
Santa Clara, CA 95050

Tel: 408-986-1600
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Contact Person: Carol Hubler
Date: Sept 27, 2006

Device Trade Name: IVUS Enhancer
Common Name: Enhancer
Classification: Picture Archiving and Communication System, Class II Sec. 21 CFR 807.92

Predicate Devices:

In-Vision View with Measurements Module (K022940)
QCU-CMS Analytical Software Package (K011582)

Description of the Device:

IVUS Enhancer is a software product that provides capabilities for viewing and interacting with DICOM data from Intravascular Ultrasound (IVUS) studies from all vendors, other DICOM medical image data, and INDEC echoPlaque IMG/BMG IVUS files. **IVUS Enhancer's** main functionality includes viewing and playback of medical images and ancillary files, minor image analysis including some measurements, and the ability to resave image cross-sections and animations to be used in future presentations.

Intended Use of the Device:

IVUS Enhancer is a software product intended to be used to review and analyze DICOM images, primarily intravascular ultrasound (IVUS) images. **IVUS Enhancer** is intended to help qualified medical professionals enhance DICOM images by adjusting image properties, making measurements, and adding annotations for easy export to other applications. These features aid in post-procedure analysis regarding the placement of interventional devices.

Substantial Equivalence to Predicate Device:

The **IVUS Enhancer** is substantially equivalent in intended use, design, and operation characteristics to the following currently marketed devices:

Intelligent Images S.r.l. (MediMatic) In-Vision View with Measurements Module (K022940),
Medis Medical Imaging Systems B.V. QCU-CMS Analytical Software Package (K011582)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Carol Hubler
Vice President
INDEC Systems, Inc.
2210 Martin Ave.
SANTA CLARA CA 95050

NOV 2 2 2006

Re: K062985
Trade/Device Name: IVUS Enhancer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and IYO
Dated: September 26, 2006
Received: October 10, 2006

Dear Ms. Hubler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062985

Device Name: IVUS Enhancer

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Cardiovascular and Neurological Devices
510(k) Number K062985